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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/082,036	02/20/2002	Kathleen A. Elias	CYTOP002D1	9501
22434	7590	10/21/2003	EXAMINER	
BEYER WEAVER & THOMAS LLP			BRUSCA, JOHN S	
P.O. BOX 778			ART UNIT	
BERKELEY, CA 94704-0778			PAPER NUMBER	

1631

DATE MAILED: 10/21/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/082,036	ELIAS, KATHLEEN A.	
	<b>Examiner</b>	<b>Art Unit</b>	
	John S. Brusca	1631	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 11 September 2003.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 24-34 and 36-45 is/are pending in the application.
- 4a) Of the above claim(s) 39-42, 44 and 45 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 24-34, 36-38 and 43 is/are rejected.
- 7) ☒ Claim(s) 34 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 20 February 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All   b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                             | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                    | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____                                    |

**DETAILED ACTION**

***Election/Restrictions***

1. Applicant's election with traverse of the species of disease consisting of neurodegenerative diseases in the election filed 11 September 2003 is acknowledged. The traversal is on the ground(s) that the species of diseases are drawn to related inventions. This is not found persuasive because the search for each species is not coextensive.

The requirement is still deemed proper and is therefore made FINAL.

It is noted that the cancellation of claim 35 obviates election of the agents listed in claim 35. In the restriction requirement mailed 27 August 2003 a listing of species of agents in claim 34 was not clearly required, and upon further review the agents of claim 34 consisting of chemical compounds or biological material will be examined without requirement of species election.

2. Claims 39-42, 44, and 45 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected species, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the election filed 11 September 2003.

***Priority***

3. The statement regarding applications PCT/US00/13154 and a second unlisted application in the second sentence on page one of the specification is not considered to be a claim for priority because both the application number and the relationship between the nonprovisional applications are not indicated as required by 37 CFR 1.78(a)(2)(i).

***Specification***

4. The disclosure is objected to because of the following informalities: On page 1, line 3 the application number is blank and a docket number appears. The application number should be inserted and the docket number deleted.

Appropriate correction is required.

***Claim Objections***

5. Claim 34 is objected to because of the following informalities: The claim does not end in a period. Appropriate correction is required.

***Claim Rejections - 35 USC § 102***

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 24-34, and 36-38 are rejected under 35 U.S.C. 102(b) as being anticipated by Hofland et al.

The claims are drawn to a method of predicting the effect of a drug on two different cocultured cells. The effect of the drug is determined by imaging the cells subsequent to exposure to the drug. In some embodiments, the effect of the agent is on extracellular matrix deposition, the two cells exhibit a diseased condition, and the two cells are grown in different compartments in the same medium.

Hofland et al. shows in figure 3 a visual assay of cells that were cocultured in a transwell apparatus. The cells were epithelial and fibroblast cells from human breast cancer tissue. The

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cells were treated with epidermal growth factor. The cells were immunostained for the presence of keratin on the extracellular surface. Hofland et al. shows that epidermal growth factor and fibroblast cells enhance growth and keratin deposition in breast cancer epithelial cells.

8. Claims 24-29, 31-34, and 36-38 are rejected under 35 U.S.C. 102(b) as being anticipated by Stearns et al.

The claims are drawn to a method of predicting the effect of a drug on two different cocultured cells. The effect of the drug is determined by imaging the cells subsequent to exposure to the drug. In some embodiments, the effect of the agent is on cell shape.

Stearns et al. shows coculture of human bone marrow endothelial cells and human epithelial prostate cancer cells. The cells are treated with IL-10 in Table 2 and with antibodies to MMP-2 and MMP-9 or antibodies to TIMP-1 in Table 1. Tables 1 and 2 show the results of the cell treatment on image determined length of microvessel formation (as depicted in figure 1). Stearns et al. show in the abstract and throughout that interleukin-10 and MMP-9/MMP-2 antibodies blocked formation of microvessels in the cultured cells.

9. Claims 24-34, 36-38, and 43 are rejected under 35 U.S.C. 102(b) as being anticipated by Zietlow et al.

The claims are drawn to a method of predicting the effect of a drug on two different cocultured cells. The effect of the drug is determined by imaging the cells subsequent to exposure to the drug. In some embodiments, the effect of the agent is on cell viability, the two cells exhibit a neurodegenerative diseased condition, in some embodiments the cells are neurons and glial cells, in some embodiments the two cells are grown in different compartments in the same medium.

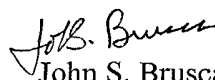
Zietlow et al. shows in the abstract and figure 1 experiments in which microglial cells and neurons are cocultured in a two-well device that shares a common culture medium. The cells are treated with FMLP. Figure 2 shows the results of imaging the cells for tyrosine hydroxylase antigen by immunofluorescent microscopy as detailed in the methods section in the first column of page 1659. Figure 2 shows the results of viability of tyrosine hydroxylase cells after the coculture experiments.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to John S. Brusca whose telephone number is 703 308-4231. The examiner can normally be reached on M-F 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on 703 308-4025. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703 308-0196.

  
John S. Brusca  
Primary Examiner  
Art Unit 1631

jsb